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(54) Single use disposable needleless injector

Nadelloser Einweg-Injektor

Injecteur sans aiguille à usage unique

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Description

Background of the Invention

1. Field of the Invention

[0001] This invention relates generally to hypodermic injection devices, and more particularly to a single use needleless injection device that utilizes a fine high pressure stream of the liquid medicament to penetrate the skin and deliver the desired dosage into a patient's body.

2. Description of Related Information

[0002] The needleless jet injection art dates from the 1940's. The ability to perform needleless hypodermic penetrations developed as a result of observations of accidental injection of fluids into workers handling high pressure hydraulic lines having pinhole leaks.

[0003] The resultant early jet injector devices actually commercialized tended toward being large, complex units generally adapted to retain sufficient quantities of medicament for repeated injections. Most of these devices were intended for usage in fixed site situations such as army induction centers or mass innoculations at clinics.

[0004] Smaller portable devices also have been developed which are powered by compressed gas or springs. For the most part, these devices are complex and multi-component as well as requiring dismantling, reassembly and sterilization between uses.

[0005] Attempts have been made to simplify the usage of needleless injectors and make them more practical for individuals required to self-administer medicaments. Several devices have been developed with single use cartridges containing a liquid medicament intended for use with a reuseable driver mechanism. Representative of these are United States Patent 4,874,367 which teaches a single use cartridge and a reuseable spring powered driver mechanism and United States Patent 4,941,880 which teaches a prefilled medicament ampule with a reuseable compressed gas powered drive mechanism. The devices taught in the '367 and '880 patents are complex and multi-component. They have a mass and size similar to a two cell "C" flashlight.

[0006] A single use device employing a gas powered drive mechanism is taught in United States Patent 5,009,637. The teachings describe a threaded socket for a filled vial to vary the dose delivered. The '637 device has numerous parts and requires a fracturable high pressure cylinder or ampule to contain the compressed gas.

[0007] Size and complexity of the drive mechanism has largely precluded the use of needleless injectors for stand-by self administration of medicaments for acute insect bite allergy reactions, migraine attacks, infertility, impotence and the like. The majority of the devices in the prior art are designed to be reusable, hence they must be reloadable, thereby increasing their physical complexity and mass. As a result, most stand-by self administration kits currently available use either prefilled hypodermic syringes, or sealed ampules and a standard hypodermic syringe. While these kits are satisfactory for their intended use, in many states possession and disposal of syringes is regulated, thereby affecting their availability and use. Further, self administration of an injectable medicament, either with a prefilled syringe or a sealed ampule with a standard syringe, particularly under conditions of a physical stress such as an allergy or migraine attack requires a high level of control and skill on the part of the patient. A single use prefilled needleless hypodermic injection device which was simple to use, not complex to manufacture, hence available at a reasonable cost, designed not to be reuseable, thus likely not subject to the regulatory requirements regarding possession and disposal of hypodermic syringes, would represent an advance to the art. Such a device is described hereinbelow.

[0008] United States patent, 2, 762, 369 describes a hypodermic injector with adjustable impact plunger. In the hypodermic injector, there is an assembly comprising an elongated body, an ampule holder detachably connected to one end thereof and adapted to hold an orificed ampule having liquid and a follower in the bore thereof, primary and secondary plungers mounted within said body for engaging and propelling said follower to discharge liquid from said ampule at two different sequential pressures, said primary plunger being associated with power means within said body and adapted to propel the secondary plunger after travelling an initial distance, said primary plunger being adjustable with respect to said follower to permit varying the distance therebetween, thus varying the force of impact imposed upon the follower by the primary plunger, said power means comprising a coil spring interposed between the end of said body and said plunger head, a screw disposed within said spring and fixed to said head for compressing the spring, latch means manually rotatable within said body and having threads adapted to engage the threads of said screw to constrain it against axial movement and to disengage the threads of said screw to suddenly release the energy of the spring.

Summary of the Invention

[0009] An operable needleless hypodermic injector includes an elongate housing with a proximal end, a distal end, a longitudinal axis and a hollow bore therethrough. The housing has a reservoir at the distal end of the housing with a generally cylindrical chamber for containing an injectable liquid. The reservoir has a longitudinal axis axially aligned with the housing longitudinal axis and has a first open end adjacent the housing with a resilient stopper mounted slidably therein. The

reservoir has a distal second end with an orifice in fluid communication with the chamber. The resilient stopper serves to seal the chamber and to eject the liquid from the chamber, forming a stream at the orifice when the stopper is moved distally in the chamber. An elongate piston is mounted for axial movement within the housing bore. The injector has elements for axially biasing the piston distally within the bore. The piston has an armed position wherein it is positioned proximally within the bore in opposition to the biasing elements. Further the injector has elements to retain the piston in the armed position causing the biasing elements to have potential energy and elements including a plunger to release the piston from the armed position thereby allowing the energy of the biasing elements to urge a distal axial movement of the piston. With a distal movement, the piston engages and causes a distal axial movement of the stopper through the chamber which ejects the liquid through the orifice forming a stream of the liquid which will make a hypodermic penetration when the orifice is placed adjacent dermal tissue. The injector further has elements which prevent the piston from being retained in the armed position after the release elements are released.

[0010] The injector of this invention is characterised in that the needleless hypodermic injector is a disposable single use needleless hypodermic injector in which reuse is prevented by withdrawal of the plunger into the housing by the distal axial movement of the piston, as described in claim 1.

[0011] In one embodiment, the biasing elements for distally axially biasing the piston include a helical compression spring coaxially mounted about the piston. The spring is compressed between the housing and the piston when the piston is in the armed position. The axial force necessary to compress the spring is applied to the housing primarily as a radial force by the retention elements so that the housing central portion is not under any substantial axial load when the piston is retained in the armed position.

[0012] The injector housing includes an annular inwardly directed shoulder defining an inner dimension transverse the housing axis. The elongate piston has at least two cantilevers extending proximally therefrom. Each cantilever has a radially outwardly directed projection for engaging the shoulder and a radially inwardly directed protuberance. The cantilevers define a recess in the piston having an inside dimension transverse to the longitudinal axis. The elongate piston has an elongate plunger with a proximal end and a distal end positioned for slidable movement within the recess. The plunger has a large dimension portion transverse the longitudinal axis and a small dimension portion transverse the longitudinal axis located proximally adjacent to the large dimensional portion. When the plunger is positioned so that the large dimension portion contacts the protuberances on the cantilevers and the piston is in the armed position, inward flexion of the cantilever is prevented and the projections on the cantilevers engage the shoulder on the housing retaining the piston in the armed position. The piston is releaseable from the armed position by application of a distal axial force which causes axial movement of the plunger relative to the protuberances so that the small dimension portion of the plunger is adjacent to the protuberances on the cantilevers. The positioning of the small dimension portion of the plunger adjacent the cantilever protuberances allows inward flexion of the cantilevers disengaging the projections from the shoulder and releasing the piston. With the protuberances on the cantilevers being adjacent the small dimension portion, the plunger is contained in the recess by the protuberances on the cantilevers and the plunger is withdrawn into the housing with the distal movement of the piston. This withdrawal into the housing will substantially prevent the piston from being retained in the armed position thereby substantially preventing reuse of the injector.

Brief Description of the Drawings

[0013]

Fig. 1 is a perspective view of the needleless injector of the present invention.

Fig. 2 is a side elevation view of the needleless injector of Fig. 1 viewed from the distal end.

Fig. 3 is a side elevation view of the needleless injection of Fig. 1 viewed from the proximal end.

Fig. 4 is a cross-sectional view of the injector of Fig. 1 taken along the line 4,4.

Fig. 5 is an enlarged partial cross-sectional view of the proximal portion of the injector illustrating the relationship of the several components with the housing while the piston is in the armed position.

Fig.6 is an enlarged partial cross-sectional view of the proximal portion of the injector illustrating the relationship of the several components with the housing after the release means is released.

Fig. 7 is an enlarged partial cross-sectional view of the proximal portion of the injector illustrating the relationship of the several components with the housing as the piston moves distally axially.

Fig. 8 is a schematic cross section of the piston and the proximal portion of the housing of a preferred embodiment of the invention.

Fig. 9 is a schematic cross section of the piston and the proximal portion of the housing of the injector.

Detailed Description of the Invention

[0014] While this invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. The scope of the invention will be measured by the appended claims and their equivalents.

[0015] The single use needleless injector of the present invention is illustrated in Figs. 1-9 and is generally designated as 20.

[0016] For the purposes of the description of the present invention the "distal end" is meant to refer to the end of the device closest to the delivery end of the device, and "proximal end" is meant to refer to the end of the device furthest from the delivery end of the device. Referring to Figs. 1-4, injector 20 includes an elongate housing 22 having a central portion 23 with a hollow bore 24 and a longitudinal axis A, a proximal end 26 and a distal end 28. Housing 22 has a reservoir 30 mounted at distal end 28. The reservoir has a generally cylindrical chamber 32 defining a longitudinal axis B generally aligned with longitudinal axis A of housing 22 for containing an injectable liquid 33. Chamber 32 of reservoir 30 has a first open end 34 adjacent housing 22 with a resilient stopper 36 mounted therein for slidable movement. Reservoir 30 has a second end 40 having an orifice 42 in fluid communication with chamber 32. Stopper 36 seals chamber 32 and with distal movement ejects injectable liquid 33 through orifice 42. Orifice 42 serves to form a stream S of liquid 33 when stopper 36 is moved distally in chamber 32.

[0017] Injector 20 further includes an elongate piston 44 mounted for axial movement within bore 24. Piston 44 has a proximal end 46 and a distal end 48. Injector 20 has a biasing element to axially bias piston 44 to distal end 28 of housing 22. In a preferred embodiment shown in Figs. 1 and 4-7, the biasing element is a helical spring 50 coaxially mounted around piston 44.

[0018] Piston 44 has an armed position, as shown in Fig.4, where piston 44 is positioned at proximal end 26 of housing 22 in opposition to spring 50. Injector 20 has elements to retain piston 44 in the armed position retaining potential energy in spring 50. Injector 20 further has elements for releasing piston 44 from the armed position allowing the energy stored in spring 50 to urge a distal axial movement of piston 44. The movement of piston 44 engages stopper 36 and causes stopper 36 to move axially through chamber 32 to eject liquid 33 through orifice 42. Stream S of liquid 33 formed at orifice 42 will make a hypodermic penetration when orifice 42 is placed adjacent dermal tissue. Injector 20 further has elements to substantially prevent piston 44 from being retained in the armed position once the release elements have been released.

[0019] Adverting to Figs. 5-7, an enlarged detail is shown of a preferred embodiment of the elements of injector 20 which retain piston 44 in the armed position, release piston 44 from the armed position and substantially prevent piston 44 from being retained in the armed position once injector 20 has been used.

[0020] In Fig. 5, the elements of injector 20 for retaining piston 44 in the armed position are shown. Housing 22 has an inwardly directed shoulder 60 which defines an inner dimension C transverse axis A, preferably located proximally within bore 24. In a preferred embodiment as shown, shoulder 60 is formed as a part of housing 22. As an alternate, shoulder 60 may be a separate component fixedly mounted in or engaging housing 22. Piston 44 has at least two cantilevers 62 extending proximally, each cantilever 62 includes a radially outwardly directed projection 64 for engaging shoulder 60 and a radially inwardly directed protuberance 66. Cantilevers 62 define a recess 68 in piston 44 with an interior dimension D transverse to longitudinal axis A.

[0021] Injector 20 further includes an elongate plunger 70 having a proximal end 72 and a distal end 74, positioned for slidable movement within recess 68 between cantilevers 62. Plunger 70 has a portion 76 having a larger dimension E transverse axis A relative to and distally adjacent a portion 78 having a smaller dimension F transverse axis A. When piston 44 is positioned proximally in the armed position, plunger 70 is positioned so that larger transverse dimension portion 76 is contacting protuberances 66, thereby preventing inward flexion of cantilevers 62 so that projections 64 engage shoulder 60 and retain piston 44 in the armed position.

[0022] One skilled in the art will recognize that cantilevers 62 may be integrally formed as part of piston 44 and resilient as in the preferred embodiment shown herein, or in the alternate, be separate elements attached to the piston.

[0023] Piston 44 is released from the armed position by application of an external distal axial force Q which causes axial movement of plunger 70 relative to protuberances 66. Plunger larger portion 76 is moved distally axially placing small dimension portion 78 adjacent protuberances 66. The placement of small dimension portion 78 adjacent protuberances 66 allows inward flexion of cantilevers 62 thereby allowing disengagement of projections 64 from shoulder 60. The disengagement of projections 64 from shoulder 60 thereby allows preferred spring 50 to urge distal axial movement of piston 44.

[0024] The distal axial movement of piston 44 results in piston 44 engaging stopper 36, moving the stopper through chamber 32 to eject contained liquid 33 in stream S through orifice 42 so that the stream will make a hypodermic penetration when orifice 42 is positioned adjacent dermal tissue.

[0025] As is shown in Figs. 6 and 7, distal axial movement of piston 44 draws plunger 70 into housing 22. When small dimension portion 78 is adjacent inward

protuberances 66, cantilever protuberances 66 contain plunger 70 at large dimension portion 76 adjacent small dimension portion 78 in recess 68, thereby causing withdrawal of plunger 70 into bore 24 of housing 22 with distal movement of piston 44.

[0026] Portion 78 of plunger 70 may proximally extend beyond housing 22 when piston 44 is retained in the proximal armed position to receive axial force Q for moving plunger 70 distally axially. Alternatively, as seen in Fig. 4, an external button 73 may be placed on housing 22 to detachably cooperate with and contact plunger proximal portion 72 for transmission of axial force Q to plunger 70.

[0027] As described above and shown schematically in Figs. 8 and 9, piston 44 is positioned proximally in housing 22 and retained in the armed position by the engagement of shoulder 60 by projections 64 on cantilevers 62. An axial tensile force is imparted on piston 44 to compress spring 50 between annular flange 45 on piston 44 and proximal portion 26 of housing 22. Generally, in prior art spring powered devices, when a piston is retained in the armed position,.a constant axial tensile force is applied to the housing elements. This constant load requires that the housing elements be constructed from materials which do not deform under the resultant stress. Generally metals are used, adding both to the difficulty of manufacture and mass of the device. In the present invention, the normal force N necessary to hold spring 50 in the compressed position is applied to shoulder 60 at proximal portion 26 of housing 22 when the piston is positioned proximally and plunger large diameter portion 76 is adjacent inward protuberance 66. Force N has an axial component and a radial component. In cases where the interface between shoulder 60 and projections 64 is nearly transverse axis A, i.e. angle theta approaches zero, the radial component of N is small with respect to the axial component. As in the case of the preferred embodiment where angle theta is about 70°, the radial component is large with respect to the axial component. In all cases, when the piston 44 is retained in the proximal position, the housing 22 central portion 23 is not subject to an axial load except when the release means is released.

[0028] Adverting to Fig. 5, the presence of plunger large portion 76 adjacent cantilever inward protuberance 66 prevents inward flexion of cantilevers 62, thereby forcing projections 64 against shoulder 60. This conversion of an axial force to primarily a radial force on housing 22 has the result that housing central portion 23 is not subject to a significant axial force when piston 44 is retained in the armed position. Housing central portion 23 therefore does not have a materials requirement that it not deform under axial load, which the prior art spring powered devices have had to contend with. The instant invention housing 22, piston 44 and plunger 70 may be formed from thermoplastics such as acrylonitrile/butadiene/styrene, polypropylene, polyethylene, polycarbonate, polyacetal, polyesters and the like. Further, as shown in Fig. 4, since the retention load is concentrated in the shoulder area of the housing, shoulder 60 may be integrally formed as part of housing 22 or another material such as a metal insert may be bonded, adhesively, mechanically and the like, to housing 22 as a separate component.

[0029] Referring again to Fig. 4, reservoir 30 is mounted at distal end 28 of housing 22 by interacting element 80 on end 28 and a conjugate element 82 on open end 34 of the reservoir. These elements may be threads or snap-fit elements and in a preferred embodiment, elements 80 and 82 would be constructed to be substantially non-releaseable once engaged.

[0030] Distal second end 40 of the reservoir 30 has an orifice 42 to form a stream of liquid 33 when resilient stopper 36 is moved distally in chamber 32. Orifice 42 preferably is integrally formed in a single step with formation of reservoir 30. Reservoir 30 may be formed from a thermoplastic such as polypropylene, acrylonitrile/butadiene/styrene, polyethylene, polyacetal, polyester and the like. Orifice 42 preferably is sealed by a cap 84 which would be removed prior to use of the injector. Device 20 preferably has tamper evidence elements to provide visual evidence that cap 84 has been moved from its initial position. The tamper evidence elements may include a frangible seal connecting cap 84 to reservoir 30.

[0031] Plunger 78 preferably has elements for preventing its unintentional movement and release of piston 44 such as a cap 86 or cover over proximal end 26 of the housing and tamper evidence elements to provide visual evidence that the cap or cover has been moved from its initial position. The tamper evidence elements may include a frangible seal.

[0032] Reference has been made to the presently invented needleless injection device being single use. The elements in a preferred embodiment of the device which serve to render the present invention single use or substantially non-reuseable and which also would generally render the device resistant to reuse include but are not limited to the non-releaseability of the reservoir attachment elements to the housing and the withdrawal of the elongate plunger into the housing by the piston when it is released. In order to overcome these provisions for rendering the device single use or to reuse it, the housing of the device must be breached, rendering it substantially non-functional.

[0033] Thus, it can be seen that the present invention provides a simple to manufacture, easily used, difficult to misuse needleless injector which will be suitable for stand-by self administration of injectable medicaments.

Claims

1. An operable needleless hypodermic injector (10) comprising:

   an elongate housing (22) having a proximal

end (26), a distal end (28), a hollow bore (24) therethrough and a longitudinal axis (A);

a reservoir (28) at said distal end (28) of said housing (22), said reservoir (28) having a generally cylindrical chamber (32) defining a longitudinal axis (B) for containing an injectable liquid (33), said chamber (32) being axially aligned with said longitudinal axis (A) of said housing (22), said reservoir (28) having a first open end (34) adjacent said housing (22), a resilient stopper (36) mounted slidably within said chamber (32), said stopper (36) for sealing said chamber (32) and for ejecting the liquid (33) from said chamber (32), and a distal second end (40) of said reservoir (28) having an orifice (42) in fluid communication with said chamber (32), said orifice (42) serving to form a stream (S) of the liquid (33) when said stopper (36) is moved distally in said chamber (32);

an elongate piston (44) mounted for axial movement within said bore (24) having a proximal end (46) and a distal end (48);

said injector (10) having:

biasing means (50) for axially biasing said piston (44) to said distal end (28) of said housing (22), said piston (44) having an armed position wherein said piston (44) is positioned proximally in said housing (22) in opposition to said biasing means (50), said biasing means (50) thereby having potential energy,

retention means (60, 64, 76) for retaining said piston (44) in said armed position,

release means including a plunger (70) for releasing said piston (44) from said armed position and allowing said energy of said biasing means (50) to urge a distal axial movement of said piston (44), said movement of said piston (44) to engage and to cause a distal axial movement of said stopper (36) through said chamber (32) thereby ejecting the liquid (33) through said orifice (42), so that the stream (S) of the liquid (33) being formed at said orifice (42) will make a hypodermic penetration when said orifice (42) is placed adjacent dermal tissue,

and preventing means (26, 70) for preventing said piston (44) from being retained in said armed position after said release means is released;

characterised in that the needleless hypodermic injector (10) is a disposable single use needleless hypodermic injector (10) wherein the release means comprises a plunger (70) slidably disposed within a recess (68) defined by at least two cantilevers (62) extending proximally from the piston (44), the reuse being prevented by withdrawal of the plunger (70) into the housing (22) by the distal axial movement of the piston (44).

2. The injector (10) of claim 1 wherein said biasing means (50) for distally axially biasing said piston (44) is a spring (50).

3. The injector (10) of claim 1 further including:

an annular inwardly directed shoulder (60) defining an inner dimension (C) transverse to said longitudinal axis (A) located within said housing (22);

each of said cantilevers (62) including a radially outwardly directed projection (64) for engaging said shoulder (60) and a radially inwardly directed protuberance (66), the recess (68) defined by said cantilevers (62) having an inside dimension (D) transverse said longitudinal axis (A);

said elongate plunger (70) having a proximal end (72) and a distal end (74) being positioned for slidable movement within said recess (68), said plunger (70) having a large dimension portion (76) transverse said longitudinal axis (A) and a small dimension portion (78) transverse said longitudinal axis (A) located proximally from and adjacent said large dimension portion (76);

said plunger (70) being positioned so that said large dimension portion (76) is contacting said protuberances (66) when said piston (44) is in said armed position, thereby preventing inward flexion of said cantilevers (62) causing said projections (64) on said cantilevers (62) to engage said shoulder (60) and to retain said piston (44) in said armed position;

said piston (44) being releasable from said armed position by application of a distal axial force causing axial movement of said plunger (70) relative to said protuberances (66) so that said small transverse portion is adjacent said protuberances (66), thereby allowing inward flexion of said cantilevers (62) so that said projections (64) disengage said shoulder (60) thereby releasing said piston (44) to move distally; and

said protuberances (66) on said cantilevers (62) being adjacent said small transverse portion of said plunger (70) with said release means being released, thereby containing said plunger (70) in said recess (68) at said large dimension portion (76) and moving said plunger (70) distally with said distal movement of said piston (44).

4. The injector (10) of claim 3 wherein said proximal end (72) of said plunger (70) projects from said housing (22) when said piston (44) is in said armed position, said proximal end (72) serving as a trigger for receiving said external distal axial force for releasing said release means for releasing said piston (44) from said armed position.

5. The injector (10) of claim 4 having means for preventing unintentional release and having tamper evidence means for providing visual indication that said means for preventing unintentional release has been moved from its original position.

6. The injector (10) of claim 1 wherein said reservoir (28) is fastened at said distal end (28) of said housing (22) by means of interacting elements including a first element (80) at said distal end (28) of said bore (24) of said housing (22) and a second conjugate element (82) on said open end (34) of said reservoir (28).

7. The injector (10) of claim 6 wherein said first and second elements (80, 82) are non-releasable.

8. The injector (10) of claim 1 wherein said housing (22) and said piston (44) are formed from a thermoplastic.

9. The injector (10) of claim 1 wherein said reservoir (28) is formed from a thermoplastic and said orifice (42) in said distal second end (40) of said reservoir (28) is integrally formed in a single step with said formation of said reservoir (28).

Patentansprüche

1. Betriebsbereiter nadelloser Subkutaninjektor (10), aufweisend:

   ein langgestrecktes Gehäuse (22) mit einem proximalen Ende (26), einem distalen Ende (28), einer hindurchgehenden hohlen Bohrung (24) und einer longitudinalen Achse (A);
   ein Reservoir (28) an dem distalen Ende (28) des Gehäuses (22), wobei das Reservoir (28) eine allgemein zylindrische Kammer (32) aufweist, die eine longitudinale Achse (B) zum Aufnehmen einer injizierbaren Flüssigkeit (33) definiert, wobei die Kammer (32) axial mit der longitudinalen Achse (A) des Gehäuses (22) ausgefluchtet ist, das Reservoir (28) ein erstes offenes Ende (24) angrenzend an das Gehäuse (22) aufweist, einen nachgiebigen Stopper (36), der gleitend in der Kammer (32) angebracht ist, wobei der Stopper (36) zum Abdichten der Kammer (32) und zum Ausstoßen der Flüssigkeit aus der Kammer (32) dient, und wobei ein distales zweites Ende (40) des Reservoirs (28) eine Öffnung (42) in Fluidverbindung mit der Kammer (32) aufweist, wobei die Öffnung (42) dazu dient, einen Strom (S) der Flüssigkeit (33) zu bilden, wenn der Stopper (36) distal in der Kammer (32) bewegt wird;
   ein langgestreckter Kolben (44), der für axiale Bewegung innerhalb der Bohrung (24) eingebaut ist, wobei er ein proximales Ende (46) und ein distales Ende (48) besitzt;
   wobei der Injektor (10) aufweist:
   ein Vorspannmittel (50) zum axialen Vorspannen des Kolbens (44) zum distalen Ende (28) des Gehäuses (22) hin, wobei der Kolben (44) eine spritzbereite Position einnimmt, in der der Kolben (44) proximal in dem Gehäuse (22) gegenüber dem Vorspannmittel (50) positioniert ist, wobei das Vorspannmittel (50) infolgedessen potentielle Energie aufweist,
   Festhaltemittel (60, 64, 76) zum Festhalten des Kolbens (44) in der spritzbereiten Position,
   Freigabemittel, die einen Plunger (70) einschließen, zum Freigeben des Kolbens (44) aus der spritzbereiten Position und zum Ermöglichen, daß die Energie des Vorspannmittels (50) auf eine distale axiale Bewegung des Kolbens (44) drängt, wobei die Bewegung des Kolbens (44) dazu dient anzugreifen und eine distale axiale Bewegung des Stoppers (36) durch die Kammer (32) zu verursachen, wodurch die Flüssigkeit (33) durch die Öffnung (42) ausgestoßen wird, so daß der Strom (S) der Flüssigkeit (33), der an der Öffnung (42) erzeugt wird, eine subkutane Penetration durchführt, wenn die Öffnung (42) angrenzend an das Hautgewebe plaziert wird,
   und Verhinderungsmittel (26, 70) zum Hindern des Kolbens (44) daran, in der spritzbereiten Position festgehalten zu werden, nachdem das Freigabemittel gelöst worden ist;
   dadurch gekennzeichnet, daß der nadellose Subkutaninjektor (10) ein verfügbarer, nadelloser, subkutaner Einmalgebrauchs-Injektor (10) ist, wobei das Freigabemittel einen Plunger (70) gleitfähig in einer Ausnelunung (68) enthält, die durch mindestens zwei Ausleger (62) definiert ist, welche sich proximal vom Kolben (44) aus erstrecken, wobei die Wiederbenutzung durch Zurückziehen des Plungers (70) in das Gehäuse (22) durch die distale, axiale Bewegung des Kolbens (44) verhindert wird.

2. Injektor (10) nach Anspruch 1, beim dem das Vorspannmittel (50) für das distale, axiale Vorspannen des Kolbens (44) eine Feder (50) ist.

3. Injektor (10) nach Anspruch 1, weiter aufweisend:

eine ringförmige, nach innen gerichtete Schulter (60), die eine innere Dimension (C) quer zu der longitudinalen Achse (A) definiert und in dem Gehäuse (22) plaziert ist, wobei jeder der Ausleger (62) einen radial nach außen gerichteten Vorsprung (44) zum Angreifen an der Schulter (60), sowie einen radial nach innen gerichteten Wulst (66) umfaßt, wobei die durch die Ausleger (62) definierte Ausnehmung (68) eine innere Dimension (D) quer zu der longitudinalen Achse (A) aufweist; wobei der langgestreckte Plunger (70) ein proximales Ende (72) und ein distales Ende (74) besitzt, die für gleitende Bewegung innerhalb der Ausnehmung (68) positioniert sind, wobei der Plunger (70) einen Abschnitt (76) großer Dimension quer zu der longitudinalen Achse (A) und einen Abschnitt (78) kleiner Dimension quer zur longitudinalen Achse (A) aufweist, die proximal ab dem und angrenzend an dem Abschnitt (76) großer Dimension plaziert ist;
wobei der Plunger (70) so positioniert ist, daß der Abschnitt (76) großer Dimension die Wülste (66) berührt, wenn der Kolben (44) sich in der spritzbereiten Position befindet, wodurch eine Einwärtsbiegung der Ausleger (62) verhindert wird und die Vorsprünge (64) der Ausleger (62) veranlaßt werden, an der Schulter (60) anzugreifen und um den Kolben (44) in der spritzbereiten Position festzuhalten,
wobei der Kolben (44) durch Aufbringen einer distalen, axialen Kraft aus der spritzbereiten Position freilaßbar ist, was eine axiale Bewegung des Plungers (70) relativ zu den Wülsten (66) verursacht, so daß der kleine Querabschnitt an die Wülste (66) angrenzt, wodurch eine Einwärtsbiegung der Ausleger (62) ermöglicht wird, so daß die Vorsprünge (64) sich von der Schulter (60) ablösen, wodurch der Kolben (44) freigegeben wird, um sich distal zu bewegen;
wobei die Wülste (66) der Ausleger (62) an den kleinen Querabschnitt des Plungers (70) angrenzen, wobei die Freigabemittel gelöst werden, wodurch der Plunger (70) in die Ausnehmung (68) bei dem Abschnitt (76) großer Dimension aufgenommen wird, und wodurch der Plunger (70) distal mit der distalen Bewegung des Kolbens (44) bewegt wird.

4. Injektor (10) nach Anspruch 3, bei dem das proximale Ende (72) des Plungers (70) vom Gehäuse (22) vorspringt, wenn sich der Kolben (44) in der spritzbereiten Position befindet, wobei das proximale Ende (72) als Auslöser zum Empfangen der äußeren, distalen, axialen Kraft zum Freigeben der Freigabemittel zwecks Freigeben des Kolbens (44) aus der spritzbereiten Position dient.

5. Injektor (10) nach Anspruch 4, der Mittel zum Verhindern einer unbeabsichtigten Freigabe aufweist, und Mißbrauchnachweismittel zum Liefern einer visuellen Anzeige darüber aufweist, daß die Mittel zum Verhindern einer unbeabsichtigten Freigabe aus ihrer ursprünglichen Position herausbewegt worden sind.

6. Injektor (10) nach Anspruch 1, bei dem das Reservoir (28) am distalen Ende (28) des Gehäuses (22) durch wechselwirkende Elemente befestigt ist, die ein erstes Element (80) am distalen Ende (28) der Bohrung (24) des Gehäuses (22), sowie ein zweites konjugiertes Element (22) am offenen Ende (34) des Reservoirs (28) umfassen.

7. Injektor (10) nach Anspruch 6, bei dem die ersten und zweiten Elemente (80, 82) nicht freigebbar sind.

8. Injektor (10) nach Anspruch 1, bei dem das Gehäuse (22) und der Kolben (44) aus einem thermoplastischen Material hergestellt worden sind.

9. Injektor (10) nach Anspruch 1, bei dem das Reservoir (28) aus einem thermoplastischen Material hergestellt ist, und die Öffnung (42) im distalen zweiten Ende (40) des Reservoirs (28) integral in einem einzigen Schritt bei der Herstellung des Reservoirs (28) gebildet ist.

Revendications

1. Dispositif d'injection hypodermique opérationnel sans aiguille (10) comprenant:

un logement allongé (22) comportant une extrémité proximale (26), une extrémité distale (28), un alésage creux (24) le traversant et un axe longitudinal (A);
un réservoir (28) au niveau de ladite extrémité distale (28) dudit logement (22). ledit réservoir (28) comportant une chambre généralement cylindrique (32), définissant un axe longitudinal (B), destinée à contenir un liquide injectable (33), ladite chambre (32) étant alignée axialement avec ledit axe longitudinal (A) dudit logement (22), ledit réservoir (28) comportant une première extrémité ouverte (34), adjacente audit logement (22), un bouchon résilient (36), monté par glissement dans ladite chambre (32), ledit bouchon (36) servant à fermer de façon étanche ladite chambre (32) et à éjecter le liquide (33) de ladite chambre (32), et une deuxième extrémité distale (40) dudit réservoir (28) comportant un orifice (42), en communication de fluide avec ladite chambre (32), ledit orifice (42) servant à former un courant (S) de

liquide (33) lors d'un déplacement distal dudit bouchon (36) dans ladite chambre (32); un piston allongé (44), monté de sorte à pouvoir effectuer un déplacement axial dans ledit alésage (24), comportant une extrémité proximale (46) et une extrémité distale (48);

le dit dispositif d'injection (10) comportant:

un moyen poussoir (50) pour pousser axialement ledit piston (44) vers ladite extrémité distale (28) dudit logement (22), ledit piston (44) comportant une position armée dans laquelle ledit piston (44) est agencé de manière proximale dans ledit logement (22), opposé audit moyen poussoir (50), ledit moyen poussoir (50) disposant ainsi d'une énergie potentielle, un moyen de retenue (60, 64, 76) pour retenir ledit piston (44) dans ladite position armée.

un moyen de dégagement englobant un plongeur (70) pour dégager ledit piston (44) de ladite position armée et permettre à ladite énergie dudit moyen poussoir (50) à entraîner un déplacement axial distal dudit piston (44), ledit déplacement dudit piston (44) étant destiné à engager ledit bouchon (36) à travers ladite chambre (32) et à entraîner un déplacement axial distal de celui-ci, pour éjecter ainsi le liquide (33) à travers ledit orifice (42), de sorte que le courant (S) de liquide (33) formé au niveau dudit orifice (42) assure une pénétration hypodermique lorsque ledit orifice (42) est adjacent au tissu dermique,

et un moyen de prévention (26, 70) pour prévenir la retenue dudit piston (44) dans ladite position armée après le relâchement dudit moyen de dégagement;

caractérisé en ce que le dispositif d'injection hypodermique sans aiguille (10) est un dispositif d'injection hypodermique sans aiguille à usage unique, à jeter (10), le moyen de dégagement comprenant un plongeur (70), agencé par glissement dans un évidement (68), défini par au moins deux éléments en porte-à-faux (62), s'étendant dans une direction proximale à partir du piston (44), la réutilisation étant empêchée par la rentrée du plongeur (70) dans le logement (22) par suite du déplacement axial distal du piston (44).

2. Dispositif d'injection (10) selon la revendication 1, dans lequel ledit moyen poussoir (50) destiné à exercer une poussée axiale distale audit piston (44) est un ressort (50).

3. Dispositif d'injection (10) selon la revendication 1, englobant en outre:

un épaulement annulaire dirigé vers l'intérieur (60), définissant une dimension interne (C) transversale audit axe longitudinal (A), agencé dans ledit logement (22); chacun desdits éléments en porte-à-faux (62) englobant une saillie dirigée radialement vers l'extérieur (64), destinée à s'engager dans ledit épaulement (60), et une protubérance dirigée radialement vers l'intérieur (66) l'évidement (68) défini par lesdits éléments en porte-à-faux (62) ayant une dimension interne (D) transversale audit axe longitudinal (A);

ledit plongeur allongé (70) comportant une extrémité proximale (72) et une extrémité distale (74), et étant agencé en vue d'un déplacement par glissement dans ledit évidement (68), ledit plongeur (70) comportant une partie à dimension accrue (76), transversale audit axe longitudinal (A) et une partie à dimension réduite (78), transversale audit axe longitudinal (A), agencée de manière proximale par rapport à ladite partie à dimension accrue (76) et adjacente à celle-ci;

ledit plongeur (70) étant positionné de sorte que ladite partie à dimension accrue (76) contacte lesdites protubérances (66) lorsque ledit piston (44) se trouve dans ladite position armée, empêchant ainsi une flexion vers l'intérieur desdits éléments en porte-à-faux (62), entraînant l'engagement desdites saillies (64) sur lesdits éléments en porte-à-faux (62) dans ledit épaulement (60) et à retenir ledit piston (44) dans ladite position armée;

ledit piston (44) pouvant être dégagé de ladite position armée par application d'une force axiale distale. entraînant le déplacement axial dudit plongeur (70) par rapport auxdites protubérances (66), de sorte que ladite partie transversale réduite est adjacente auxdites protubérances (66), permettant ainsi une flexion vers l'intérieur desdits éléments en porte-à-faux (62), de sorte que lesdites saillies (64) sont dégagées dudit épaulement (60), relâchant ainsi ledit piston (44) en vue de son déplacement distal;

et

lesdites protubérances (66) sur lesdits éléments en porte-à-faux (62) étant adjacentes à ladite partie transversale réduite dudit plongeur (70), ledit moyen de dégagement étant relâché, retenant ainsi ledit plongeur (70) dans ledit évidement (68) au niveau de ladite partie à dimension accrue (76) et déplaçant ledit plongeur (70) dans une direction distale par suite dudit déplacement distal dudit piston (44).

4. Dispositif d'injection (10) selon la revendication 3, dans lequel ladite extrémité proximale (72) dudit plongeur (70) déborde dudit logement (22) lorsque ledit piston (44) se trouve dans ladite position

armée, ladite extrémité proximale (72) servant de déclencheur pour recevoir ladite force axiale distale externe en vue du relâchement dudit moyen de dégagement, pour dégager ledit piston (44) de ladite position armée.

5. Dispositif d'injection (10) selon la revendication 4, comportant un moyen pour empêcher un dégagement intempestif et comportant des moyens témoins d'une ouverture pour fournir une indication visuelle indiquant que ledit moyen destiné à empêcher un dégagement intempestif a été déplacé de sa position d'origine.

6. Dispositif d'injection (10) selon la revendication 1, dans lequel ledit réservoir (28) est fixé à ladite extrémité distale (28) dudit logement (22) par l'intermédiaire d'éléments interactifs englobant un premier élément (80) au niveau de ladite extrémité distale (28) dudit alésage (24) dudit logement (22) et un deuxième élément conjugué (82) sur ladite extrémité ouverte (34) dudit réservoir (28).

7. Dispositif d'injection (10) selon la revendication 6, dans lequel lesdits premier et deuxième éléments (80, 82) sont non amovibles.

8. Dispositif d'injection (10) selon la revendication 1, dans lequel ledit logement (22) et ledit piston (44) sont formés à partir d'une matière thermoplastique.

9. Dispositif d'injection (10) selon la revendication 1, dans lequel ledit réservoir (28) est composé d'une matière thermoplastique, ledit orifice (42) dans ladite deuxième extrémité distale (40) dudit réservoir (28) étant formé d'une seule pièce au cours d'une seule étape lors de ladite formation dudit réservoir (28).

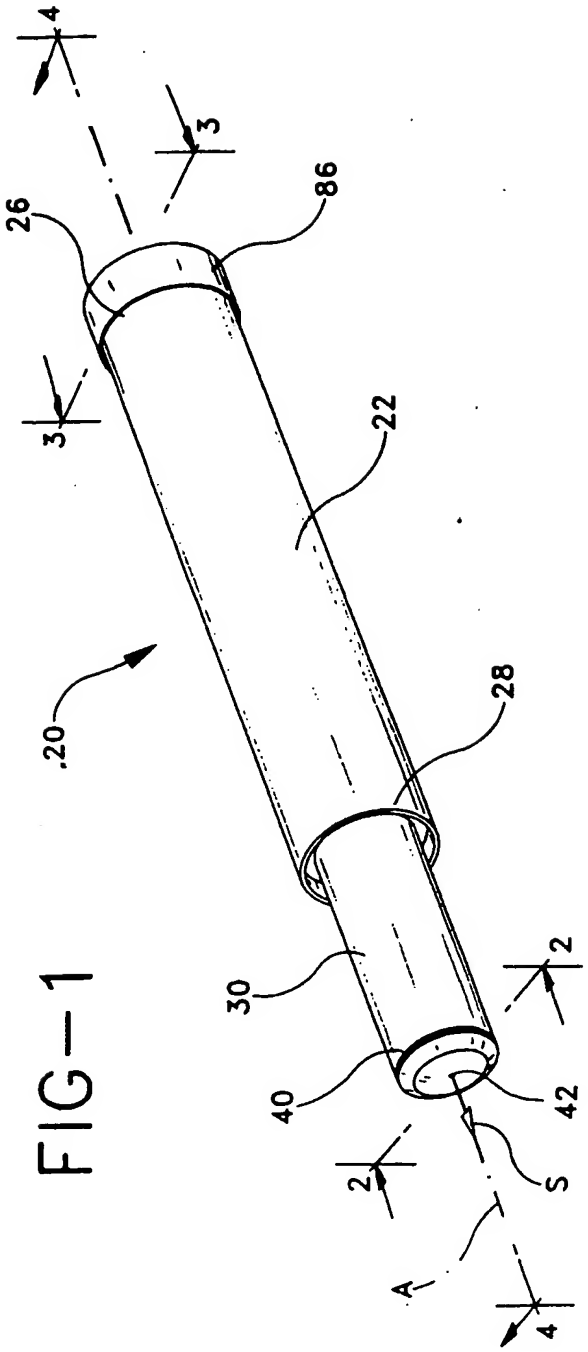

FIG-1

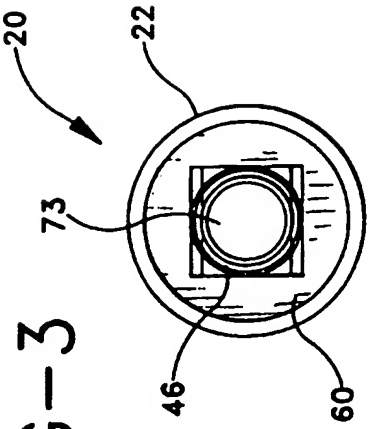

FIG-3

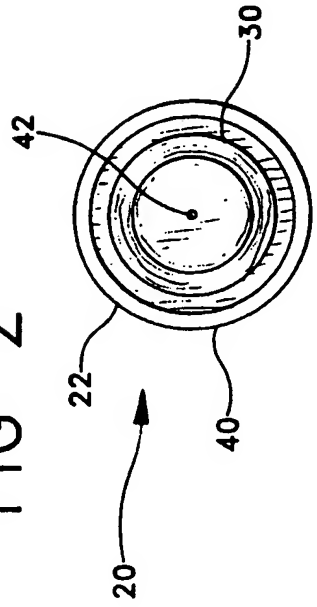

FIG-2

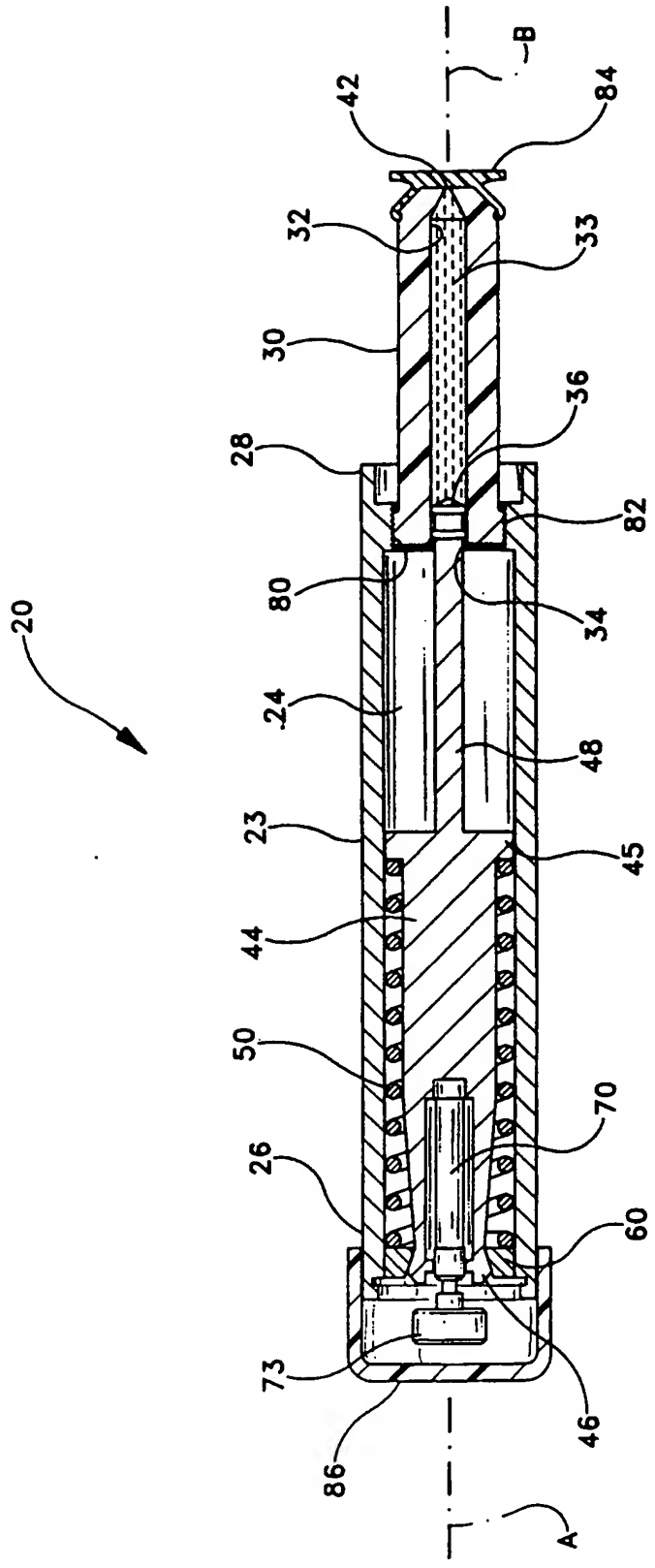

FIG-4

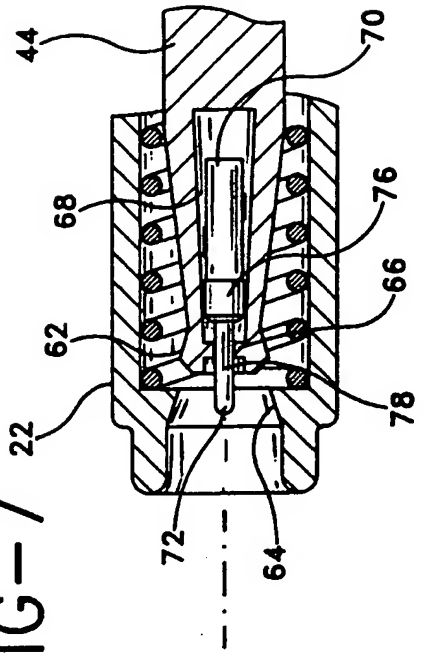

FIG-7

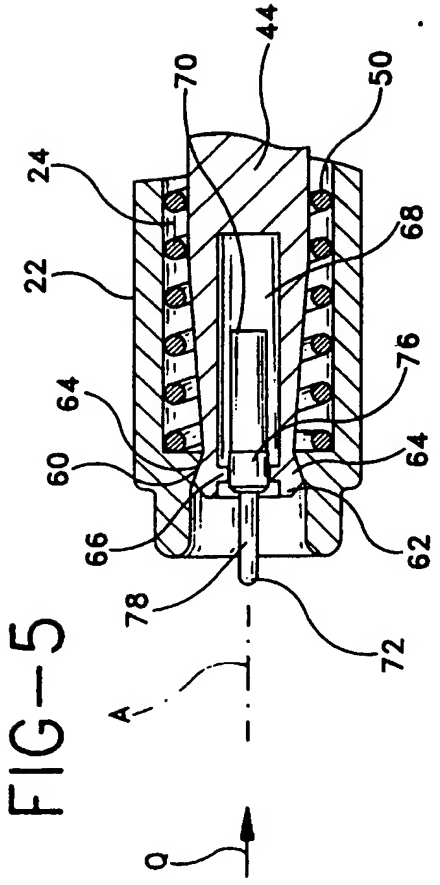

FIG-5

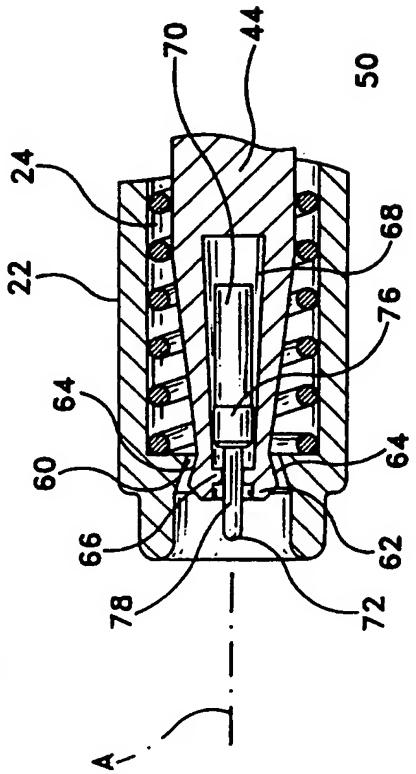

FIG-6

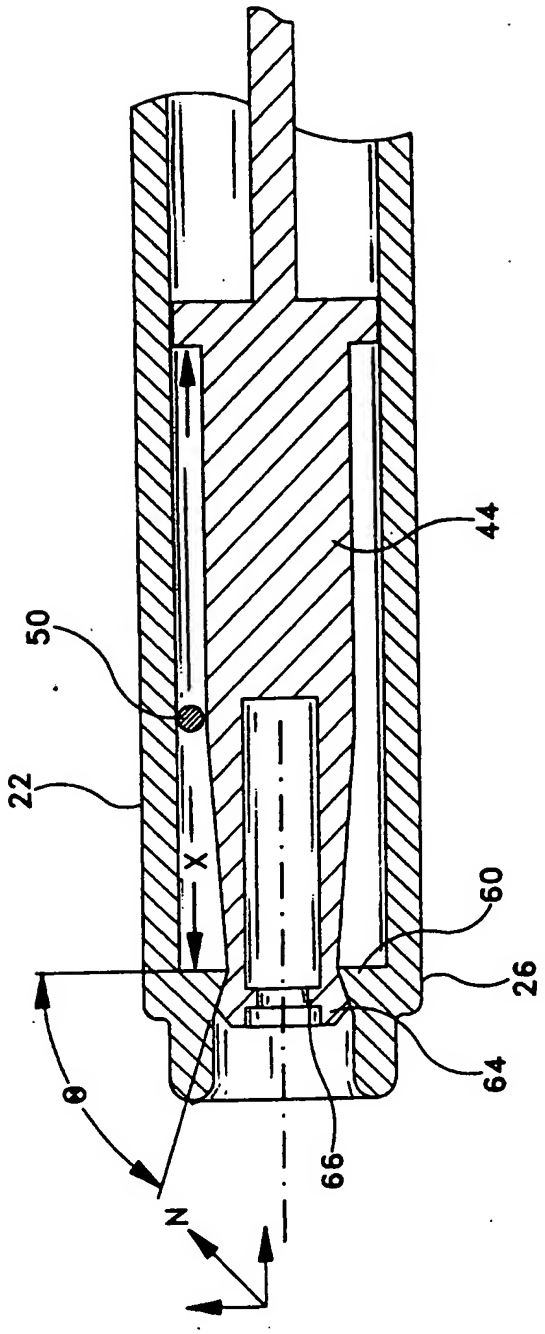

FIG-8

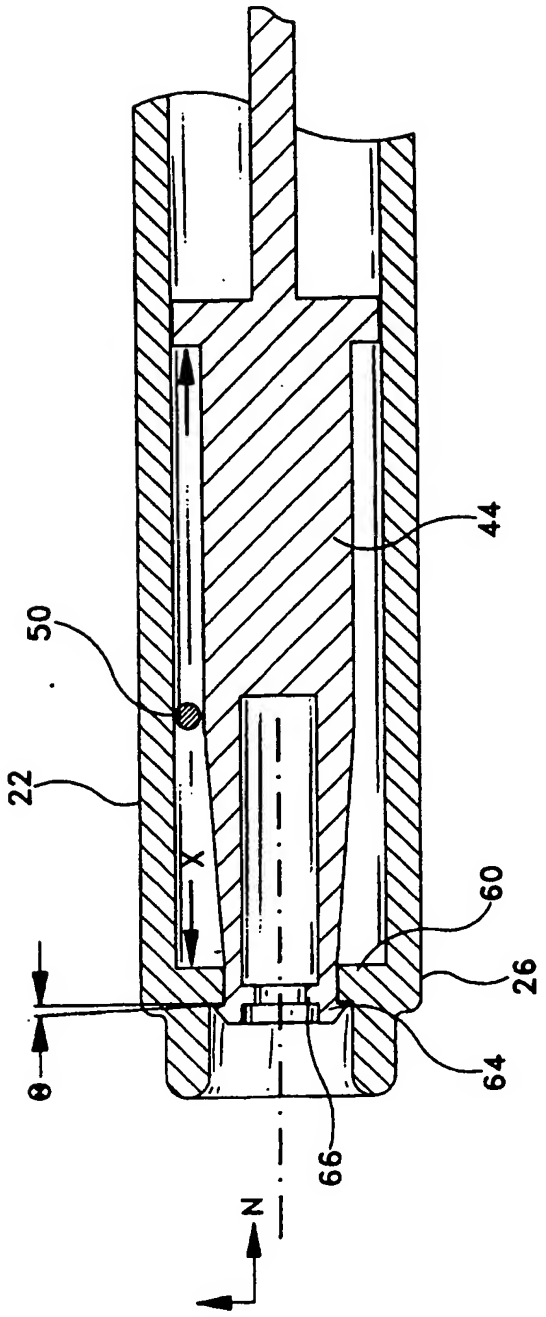

FIG-9